MEMORANDUM

SUBJECT: EFED RED Chapter for Malathion
PC Code 057701; Case No. 818961
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EFED's Environmental Risk Assessment for the Malathion Reregistration Eligibility Document has been completed and accompanies this memorandum. The registration document summarizes weaknesses and uncertainties of malathion data sets, additional required data needs, and the major areas of environmental risk concern for all labeled uses of malathion. After completion of the public comment period EFED will review responses and make any revisions to the document as deemed appropriate by the Malathion Reregistration team.

EFED has summarized the major ecological issues of concern for malathion usage as follows:

1. Malathion is highly toxic to aquatic organisms at concentrations which have been monitored or are predicted to occur in association with many presently registered use patterns.

2. Malathion is potentially hazardous to reproductive success of certain species of birds and mammals at presently registered use rates. In addition, malathion may pose sublethal effects to terrestrial and aquatic organisms through neurological inhibition which may adversely impact their survival in the natural environment. These concerns are based on laboratory and field study observations, measurement of reduced acetylcholinesterase levels in exposed wildlife, and measurement of malathion residues in tissues of organisms which were adversely affected from malathion exposure.

3. Malathion is highly toxic to beneficial insects. Direct contact during application, post application contact with foliar residues, and contact with pollen transported residues have all proven toxic to honeybees. Malathion is highly toxic to aquatic larval stages of terrestrial insects when transported to water. Use of malathion in indiscriminate types of applications (fogging or broad-target aerial) to urban and rural sites is expected to impact numerous species other than the intended target insect pests.

4. Malathion has high potential to drift off target from aerial ULV applications and has been monitored at levels high enough to pose concern for non-target invertebrates as far as 200 meters from the application site (Penn. State Boll Weevil Eradication study-see RED text for details). This concern is heightened by the fact that there are presently no aerial buffers on any malathion labels.

The overall impact of malathion on the environment has likely been mitigated by several factors over its long history of usage in the United States. Some of these factors are:

1. Malathion appears to degrade rapidly in the presence of active soil microbial activity. This activity varies in certain types of soil with degradation most rapid in moist soils.

2. Malathion appears to degrade quickly in water with high pH (> 7.0).

3. In general, malathion has not been observed to be as persistent on soil or in water as some of the other organophosphate insecticides with which it competes and it displays lower acute toxicity to birds and mammals.

4. In general, large tributaries with rapid flow rates have been adequately flushed to prevent buildup of malathion to acutely toxic levels for fish. Thus, most fish kills in malathion usage areas have been in small streams or ponds where slow flow rates permitted concentrations to exceed toxic levels for fish or where heavy rainfall events to large watershed areas allowed high concentration pulse loads to impact small aquatic habitat areas.

The environmental risk is based on the use information for malathion provided by USDA, the Biological and Economic Analysis Division of OPP, and use information provided by Cheminova on behalf of all malathion formulators. Cheminova and IR4 have indicated that a number of uses which appear on present labels will no longer be supported including forest uses, tobacco, hops, and certain minor crops. Where no support was indicated for a particular use, it was excluded from the EFED assessment of potential ecological risk. Cheminova and IR4 have also provided the Agency with maximum application rates, minimum intervals, and maximum seasonal application numbers for all supported food crops. Risk assessment procedures were based on the understanding that any labels exceeding these residue tolerance testing scenario limits for food crops would be revised during the reregistration of all malathion products. Including cotton boll weevil control, malathion use totals over 3,370,000 lbs ai per year on food crops alone. Non-crop use is also extensive with over 4,170,000 lbs ai per year used for mosquito control, household uses, industrial sites, ornamental plants, forage and fodder, stored grains, roadways, forest lands, parks, ornamental turf, farmsteads and lots, cemeteries, golf courses, and fallow land. The extent of non-crop use is much less clear than that for food crop use. Maximum use rates were used to assess potential risk from non-crop uses of malathion.

Water Resources Assessment

The water resource assessment, based on the known fate properties of malathion along with extensive monitoring data, indicates the following points.

1. Malathion is routinely detected in tributaries and retention ponds near urban areas when active monitoring programs to detect malathion are undertaken.

2. Malathion appears to undergo conversion to malaoxon during the processing of surface water to drinking water and also in the presence of certain purification chemicals used in swimming pools.

3. ULV aerial applications may drift long distances and cause adverse effects in water resources such as reservoirs, ponds and streams.

4. Malathion detections in surface water are more common and at higher levels in urban areas than in areas where agricultural use predominates. EFED believes this is due to anthropogenic surface materials common to urban areas which are devoid of soil bacteria needed to degrade malathion and to multiple uses within a single watershed which drains via interconnected storm water systems to a single pond or storm water discharge point.

Ecological Risk Characterization

<u>Risk to Terrestrial Vertebrates</u>

Malathion has been shown to offer potential chronic hazard to bobwhite quail at consistent dietary concentrations equal to or above 350 ppm. Based on this data malathion may offer potential hazard to birds at application rates above 2.5 lbs ai/acre if based on typical expected residues and above 1.25 lbs ai/acre if based on maximum expected concentrations. Applications are permitted with as little as 3 day intervals and average half-life estimates on foliage range from 1 to 10 days. Effects noted in the avian

reproduction study were reduced egghatch and regressed ovaries which could indicate that early exposure to malathion may have led to the observed effects. EFED does not have data regarding long term exposure to repeated pulses of high residues and their potential relationship to chronic effects on reproduction. Direct exposure of nests could lead to exposure of eggs or juvenile birds. Laboratory data has been reviewed which indicates that developmental effects will occur when embryos of birds are exposed to malathion. The likelihood of this type of exposure is dependent on the method of application, the treated habitat type, and the time of year that applications are made. Sublethal effects to birds from acetylcholinesterase inhibition may include reduced nesting behavior, disorientation, and loss of motor coordination leading to reduced ability to cope with the daily stresses of survival under natural conditions. This is also true, to some extent for mammals, reptiles or other terrestrial organisms which, though not acutely effected, may be sublethally susceptible to inhibition of acetylcholinesterase in neural processes.

Risk to Aquatic Organisms

Exposure to aquatic habitats has been documented in numerous monitoring studies at residue levels which exceed acute levels of concern for many species of invertebrates. Based on this information it is presumed that adverse effects may have occurred, but due to lack of population effect monitoring, gone undocumented. These monitored exposure levels have also reached levels of concern for adverse effects to fish, but less often. Malathion does have a number of reported fish kill incidents associated with its use in urban scenarios. In many of these incidents certain species of fish have been observed to be more severely impacted (e.g., sticklebacks) than other species in the same location. Fewer incident reports were received for malathion use in agricultural settings, though they do occur. In most cases, agricultural incidents occurred where farm ponds receive drift or runoff from several neighboring fields. Often feeder ditches funneled runoff to the ponds during rainfall events. Based on fate data, it would appear that the length of exposure to malathion residues may be dependent on the pH conditions of the receiving waters, with acidic conditions contributing to increased persistence. Malathion does not appear to accumulate in sediments. Long term exposure to aquatic organisms would be from repeated pulse loads related to rainfall conditions (primarily in urban scenarios) or repeated drift of residues to surface waters from multiple aerial applications.

Risk to Non-Target Beneficial Insects

Malathion is a potent insecticide which is expected to impact non-target insects along with the intended target insect pests. This is especially true when use sites are not a specifically targeted agricultural field or residential/commercial site. Examples of this might be application in ground fogs designed to drift and impact flying mosquitoes (adulticide use) or application to large tracts of rangeland to combat grasshoppers in locations away from agricultural sites which could potentially be impacted by them. Honeybee studies have also indicated that foliar residues of malathion are highly toxic 48 hours after application. Numerous data regarding the high toxicity of malathion to species of insects considered beneficial has been reviewed for or referenced in the RED document.

Data Gaps

Environmental Fate

Data for the aerobic aquatic metabolism studies are considered supplemental at this time. The

deficiency of this study is the alkaline pH of the soil and water used. Degradation of malathion is highly pH dependent, with faster rates at higher pH, thus a quantitative assessment of malathion fate and persistence under acidic conditions when hydrolysis would be slower cannot be conducted. As a result EFED cannot complete a quantitative assessment of the environmental fate of malathion and its degradates in acidic environments it is likely to contact. An aerobic aquatic metabolism study (162-4) performed under pH conditions that do not favor hydrolysis is requested. EFED believes this additional information will enable a more quantitative assessment of the fate and persistence of this major use chemical in acidic aquatic environments. This request is especially relevant given the sensitivity of numerous aquatic organisms to malathion.

The anaerobic aquatic metabolism study was also conducted under alkaline conditions favoring hydrolysis, EFED believes that hydrolysis data along with open literature data on the persistence of malathion in sediments is sufficient to conclude that malathion will not persist under anaerobic conditions and therefore a repeat of this study is not required at this time..

Fate data is required for malaoxon, the oxidation product of malathion. Malaoxon is commonly believed to be the neurotoxic agent of malathion after oxidation *in vivo* and toxicity data show it to have higher acute toxicity than malathion. EFED acknowledges that maximal conversion to malaoxon under registrant submitted study conditions was low (1.8%), however, under other conditions encountered during malathion use conversion levels as high as 10.7% of applied parent have been reported (CalEPA 1993). HED has indicated that malaoxon is to be included in the tolerance expression for malathion. First tier surface water assessments were performed by making several assumptions about the properties of malaoxon relative to malathion. It is not possible to perform second tier assessments without further data specific to malaoxon. Thus, EFED is requiring data needed to predict malaoxon levels in drinking water and aquatic habitats.

In addition to data on the basic physical properties of malaoxon (solubility, partition coefficient, vapor pressure) EFED requests that the following laboratory studies be submitted for malaoxon.. Data from these studies are expected to be sufficient to perform basic fate and exposure modeling of malaoxon.

Malaoxon Study Requirements and Justification:

<u>Degradation</u>

161-1 (hydrolysis)

Malathion hydrolysis is an important route of dissipation under alkaline conditions. The phosphorothiolate ester bond of malaoxon may be more susceptible to cleavage via hydrolysis than the analogous phosophorodithioate ester in malathion.

<u>Metabolism</u>

162-1 (aerobic soil) The primary route of malathion degradation on soil is through aerobic metabolism. An open literature study (Paschal and Neville 1976) suggests malaoxon persistence may be greater on soils. Additionally, CalEPA studies have shown levels of malaoxon production exceeding 10% in certain dry, low organic content soils.

162-4 (aerobic aquatic)

Although little or no malaoxon production is observed in registrant submitted aquatic studies malaoxon has been detected in surface waters and the potential for malaoxon runoff may be heightened relative to malathion because it is expected to have higher solubility. Aerobic aquatic metabolism contributes greatly to malathion degradation.

Mobility
163-1(leaching/adsorption)
EFED is not aware of reports of malaoxon groundwater adsorption/desorption) contamination, however, malathion has contaminated groundwater in several states and has the potential to contaminate surface water through runoff. The increased polarity of malaoxon due to the substitution of oxygen for sulfur increases the expected potential of this chemical to be mobile in soil.

EFED also requests additional information on environmental malaoxon production. Because malathion is used in a large number of settings including more than 60 terrestrial field uses as well as outdoor residential uses including mosquito, Mediterranean fruitfly, and urban pest control uses, it is exposed to a large variety of environmental conditions. This extensive use is likely to result in significant exposure of nontarget organisms to malathion breakdown products. Exposures to humans and wildlife may be through contamination of food, water, and air (by suspended particles) which can result from off-target drift, runoff, and direct application.

Ecological Effect Data Requirements and Limitations of Present Data
The toxicological data, though extensive for malathion, is not complete in several key areas. In addition, much of the data is over twenty years old, and, to some extent, was not conducted in accordance with stricter standards which are required of studies presently submitted to support registration of pesticides. For example, most of the acute toxicity endpoints for aquatic organisms are based on nominal concentrations which, due to malathion's short aquatic persistence, may not be appropriate since this could lead to calculated LC50 values which are higher than would have been estimated if based on mean measured concentrations.

There are also some other areas where the data set is weak. In formulation testing only one presently supported product formulation (57% EC) was tested on 4 species (daphnid, oyster, honeybee, and sheepshead minnow). There are no submitted toxicity data on the mixture of malathion and methoxychlor, a possibly highly lethal combination for aquatic life. Acute toxicity testing (72-1 and 72-2) with this formulation is required for bluegill and *Daphnia magna*. There are no studies regarding the chronic effect levels of malathion to estuarine fish or invertebrates which could conceivably be exposed to repeated pulse load exposures for such uses as citrus and cotton. Chronic testing of technical malathion (72-4) with sheepshead minnow and mysid are required. Full life-cycle testing with fish (72-5) is held in reserve pending decision on an appropriate protocol modification. Further data to elucidate potential effects to non-target insect populations is needed though all normally required data has been satisfied at this time. Acute studies with honeybees indicate that acute contact with direct or latent residues may prove lethal for several days after application. Other beneficial insect populations may also suffer acute losses. There is some indication that amphibians could be effected by malathion exposure. Though not presently a data requirement requested by the Agency, but given what is known

about acute and chronic effect levels observed in frogs, a better understanding of potential developmental effects to this taxa is needed to improve this assessment.

Sublethal effects caused by temporary disruption of nervous system functions are difficult to use in present risk assessment procedures, because so little is know about their ultimate effect on non-target species populations. However, malathion has been shown to disrupt nesting success in sharp tailed grouse, loss of ability of laboratory mice to navigate a maze, and loss of swimming ability for fish swimming against a current. All of these effects theoretically could lead to reduced survival of certain species groups, when combined with the normal stress factors associated with survival (e.g., successful rearing of young, escape from predators, and navigation to spawning grounds).

Label Concerns for Consideration Following Public Comment Period for This Document

1. Many malathion labels presently list application rates in exceedance of 6.25 lbs ai acre.

2. All malathion labels do not specify a maximum number of applications. Some labels contain the statement "Use as Needed" when referring to maximum seasonal applications. Food crop limitations are not always based on maximum tested tolerance scenarios.

3. Malathion labels with aerial and possibly mist-blower applications do not specify protective buffer zones for aquatic habitats in accordance with spray drift data presently known for malathion or similar types of chemicals.

4. Malathion labels with multiple applications do not specify minimum intervals for each use.

5. Malathion may lead to chronic reproductive and sublethally adverse effects to sensitive species of birds**.** No precautions in the environmental hazard statement regarding the exposure of nesting birds to direct application are presently on labels.

6. Uses no longer supported remain on many malathion product labels. Newly modified labels should be reviewed for clarification and acceptance by the Agency. Certain uses (forest use on forest insects) are still listed on newest labels submitted by Cheminova, despite the fact that this use is stated as no longer supported. These uses include hops, forest use, forest trees, tobacco, peanuts, use on animals, and any uses directly over water.
7. Precautionary language on labels pertaining to storage time and stability are not clear.

Peer Reviewers Arnet Jones (Use and fate), Kevin Costello (Groundwater), Ed Fite (Ecological Risk), James Hetrick (Fate) and within the team membership (B. Montague, Richard Mahler, and Norman Birchfield).